

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:4561

ANSWERED ON:12.08.2016

Impact of Enhanced Regulatory Fees

Kamal Nath Shri ;Scindia Shri Jyotiraditya Madhavrao

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Government has recently increased the regulatory fees for testing, manufacturing and selling medicines in the country;
- (b) if so, the details thereof and the reasons therefor;
- (c) whether the hike in regulatory fees for various drugs will have any impact on the prices of drugs/medicines affecting the common man; and
- (d) if so, the details thereof and the steps taken by the Government to ensure that prices of drugs/medicines are not increased by the pharmaceutical companies due to such hike in regulatory fees?

Answer

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE

(SHRI FAGGAN SINGH KULASTE)

(a) & (b): The Government had, vide G.S.R. No.1011(E) dated 29.12.2015, published draft rules proposing to increase the fees for conduct of clinical trials; manufacturing & import permission of New Drugs; Import Registration; License for examination, test or analysis, etc. for inviting objections or suggestions from the public. The proposed revision of the fee was worked out on the basis of the fact that these had not been revised since 2002-2003. However, the notification was not finalized keeping in view the fact that separate Rules have been drafted for medical devices and the draft has been placed in public domain.

(c) & (d): The amount of testing fee is a very small fraction of the total cost of medicines and any such increase would therefore, not impact their prices. In any case, the National Pharmaceutical Pricing Authority (NPPA) regulates the prices of drugs placed in the First Schedule to the Drugs (Price Control) Order (DPCO), 2013. The prices of drugs included in the National List of Essential Medicine (NLEM) decreased in the recent past as these are linked to Wholesale Prices Index (WPI), which declined last year. Further, the prices of non-schedule drugs cannot be increased by more than 10% under DPCO, 2013.